IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DOCTOR'S DATA, INC., a Nevada corporation, Plaintiff,	)	No. l0-CV-3795
v.	)	Hon. John J. Tharp, Judge Presiding
STEPHEN J. BARRETT, M.D., NATIONAL COUNCIL AGAINST HEALTHFRAUD, INC., a California corporation, and QUACKWATCH, INC., a dissolved Pennsylvania corporation, Defendants.	)	JURY DEMAND

DOCTOR'S DATA'S *DAUBERT* MEMORANDUM IN SUPPORT OF ITS MOTION TO BAR CERTAIN EXPERT OPINIONS OF DEFENDANTS' EXPERT, DR. ANNE-MICHELLE RUHA

Doctor's Data, Inc. ("DDI"), through its attorneys, respectfully moves this Court to bar testimony and opinions proffered by Defendants' expert, Dr. Anne-Michelle Ruha, relating to matters of clinical laboratory standards and practice, including her opinions relating to DDI's urine test results report and its allegedly misleading nature. In support, DDI states as follows.

I. INTRODUCTION

DDI is a state and federally certified clinical laboratory that analyzes urine, fecal, and blood samples submitted by physicians for their patients. DDI sued the Barrett Defendants[1] after they persisted in: (1) widely publishing false Internet statements about DDI, including but not limited to claiming that DDI was a "shady lab" that conspired with "nonstandard" physicians to issue urine test result reports as a means to "defraud" and "trick" individuals into falsely believing that they suffered from "heavy metal body burden," and (2) affirmatively encouraging third-party patients – for whom DDI merely processed urine specimens consistent with physicians' ordering instructions – to file baseless lawsuits against DDI, among others. DDI's lawsuit alleges that the Barrett Defendants'

[1] The phrase "Barrett Defendants" refers to all of the named defendants, Stephen J. Barrett, M.D., National Council Against Health Fraud, Inc., and Quackwatch, Inc.

false statements and related actions constitute, *inter alia*: (1) libel *per se*, (2) libel *per quod*, (3) trademark dilution, (4) deceptive practices, and (5) civil conspiracy.

In response, the Barrett Defendants must try to convince this Court that their Internet statements are true, but they cannot. In fact, DDI has conclusively demonstrated in its motion for summary judgment on Count 5 (libel *per* se) that the Barrett Defendants' claims are false. *See DDI's Motion for Summary Judgment on Count 5 (Libel Per Se)* (addressing "falsity" of the Barrett Defendants' claims). To demonstrate the falsity of the Barrett Defendants' claims, DDI has, *inter alia*, identified pertinent federal regulations, relied upon emails by federal regulators, and produced three recognized experts in the field of clinical laboratory standards, practice, and laboratory reports to testify to the clear falsity of the Barrett Defendants' libelous statements about DDI. *Id.*

To counter DDI's regulatory evidence, which is itself a death knell for the Barrett Defendants' position, the Barrett Defendants proffer the putative "expert" testimony of Dr. Ruha, whose main expertise is in the field of snake and spider venom poisoning. While none of Dr. Ruha's purported expert opinions tips the evidentiary scales in favor of the Barrett Defendants, some are so deficient they should be barred pursuant to F.R.E. 702 and *Daubert v. Merrell Dow*, 509 U.S. 579 (1993).

First, Dr. Ruha clearly is not qualified under *Daubert* to proffer the challenged opinions here. In sum, Dr. Ruha opines that DDI's report format is "misleading" to at least some based on her experience with a handful of people with whom she spoke who saw it. Unfortunately, this venom poisoning specialist, **by her own admission**, is **not** qualified or sufficiently knowledgeable in this field to express these very opinions. In fact, she **admits** she is not qualified or sufficiently knowledgeable to express opinions in the field of clinical laboratory standards, practices and reports, which directly govern the scientific propriety of DDI's laboratory test result format.

Aside from not being "qualified" to so opine, Dr. Ruha's foregoing opinions about clinical laboratory matters also are "unreliable" under *Daubert*. For instance, Dr. Ruha possesses absolutely no experience, training, or knowledge either generally applicable to the field of clinical laboratory science or particularly applicable to clinical laboratory test report formats. Thus Dr. Ruha, in opining

that DDI's urine test result format was materially misleading, neither was aware of, nor ever consulted, federal regulatory standards and requirements for such reports. Indeed, Dr. Ruha was unaware that federal regulations and standards **require** labs to employ the very format the Barrett Defendants (and now she) label misleading. Nor did Dr. Ruha know about (or ever review) the internal emails by federal regulatory authorities -- produced in discovery in this cause -- which substantively reject the Barrett Defendants' very allegations about the purportedly fraudulent DDI test result format, which she is seeking to support with her "expert" opinions, untethered as they are to any regulatory standard or scientific basis, but solely based on her gut feel and anecdotal experience with a handful of clinical patients.

Thus, for the reasons explained in detail below, this Court should strike under *Daubert* Dr. Ruha's unqualified and unreliable opinions and testimony about clinical laboratory matters, including those relating to DDI's allegedly misleading urine test results report.

II. FACTS

DDI provides a short factual background to place Dr. Ruha's specific opinions in the context of this case and in turn why they fail under *Daubert*.

A. DDI Is A Clinical Laboratory That Analyzes Urine Samples Submitted By Physicians, Then Issues A Test Results Report To The Clinician In A Form Mandated By Law.

DDI is a clinical laboratory that analyzes urine, fecal, and blood specimens submitted by clinicians for testing for their patients. Like many clinical laboratories, Doctor's Data offers tests to analyze urine specimens. Urine is often tested to assess, among other things, the level of "heavy metals" (sometimes referred to as "toxic metals"), such as mercury or lead, within the urine sample. (Ex. 1 (Dr. Jaffe), p. 9-10; Ex. 2 (Dr. Clark), p. 11-12; Ex. 3 (Dr. Bernhoft), p. 7-14).

Physicians submit a urine sample to DDI that is either "unprovoked" or "provoked". "Unprovoked urine" is urine as it would typically occur in the patient's daily life. "Provoked urine" involves the physician first administering a "chelating agent" to the patient prior to the collection of the urine sample, which draws out heavy metals from the body's tissues. Some physicians (not all) believe laboratory testing of a "provoked urine sample" can be helpful in either of two contexts. (Ex.

1 (Dr. J), pp. 6-10; Ex. 3 (Dr. B), pp. 7-10) First, they may submit a provoked urine sample (sometimes in conjunction with an unprovoked urine sample) to assist in clinically assessing whether a patient's symptoms or condition may be from excessive levels of toxic metals within the body's tissues, sometimes referred to as "heavy metal body burden." *Id*.

Second, if "heavy metal body burden" is clinically suspected, some physicians (not all) may recommend a course of "chelation treatment," whereby "chelating agents" are periodically provided to the patient with the goal of clawing heavy metals from the patient's body and excreting them in urine. *Id*. Under this second scenario, these physicians will periodically submit provoked urine samples to DDI (or another lab) so they can compare against the patient's prior results to determine if heavy metal content is declining over time with the chelation treatments. (Ex. 3 (Dr. B), p. 17)

Many times, an ordering physician will not inform DDI whether a urine sample is "provoked" or "unprovoked." DDI does not need to know this information to analyze a submitted sample, and it is not required by law to have this information before issuing its lab test results. (Ex. 2 (Dr. C), p. 15) As with other laboratories, DDI performs the same testing protocol and uses the same test results report format whether the urine sample is "provoked" or "unprovoked. *Id*.

Federal law requires all CLIA-certified labs like DDI to identify a "reference range" anytime they report the results of any specimen, including urine. (42 CFR 493.1291). A "reference range" allows the ordering physician to assess how a patient's urine results compare to the urine results of a "typical" population. However, there is no established reference range for a provoked urine specimen because of a myriad of variables associated with obtaining provoked urine samples. Accordingly, because there is no scientifically established "reference range" for *provoked* urine, DDI identifies the reference range applicable to unprovoked urine (as it is required to do under federal law) and then includes qualifying language – in bold lettering – stating that the reference range is inapplicable if the subject is a provoked urine specimen. (Ex. 4) Doing so is an acceptable, indeed mandated, industry practice. (Ex. 2 (Dr. C), p. 15)

DDI uses the same test report form regardless of whether the specimen analyzed is

provoked or unprovoked, and an actual exemplar of a DDI's urine test results report is attached as Exhibit 4. However, below is a rough republication:

Metals	**Result**	**Ref. Range**	**W/in RR**	**Elevated**	**V. Elevated**
Lead		10	<5	---------->	
Mercury		6.5	<3	---------->	

> **Reference ranges are representative of a healthy population under non-challenged or non-provoked conditions.** No safe reference levels for toxic metals have been established. (Ex. 4)

DDI's statement **"Reference ranges are representative of a healthy population under non-challenged or non-provoked conditions**" is referred to herein as a "Qualifying Statement."

B. CLIA And At Least One Court Have Addressed And Rejected The Barrett Defendants' Claims Relating To The Allegedly Misleading Nature of DDI's Test Results Report.

The Barrett Defendants persist in defaming DDI, labeling the foregoing DDI's urine test results report as "deceptive," "misleading," "fraudulent," and "meaningless," even though the federal regulatory authorities and a court both have addressed and expressly rejected the Barrett Defendants' claims. "CLIA" -- the "The Clinical Laboratory Improvement Amendments" -- is the vehicle by which the Center for Medicare and Medicaid Services ("CMS") regulates laboratory testing of human specimens. *See* http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. Congress charged CMS with establishing CLIA standards for quality assurance and quality control that must be met by all U.S. clinical laboratories that test human specimens for health assessment or to diagnose, prevent, or treat disease. *Id.*

The Barrett Defendants have repeatedly demanded that CLIA investigate, audit, and punish DDI for its alleged "fraudulent," "misleading," and "deceptive" test report format for provoked urine samples. For instance, they repeatedly emailed CLIA, lodging their complaints, presenting their so-called "proof," and insisting on remedial action, such as:

> I remain puzzled that your agency appears unwilling to stop the fraud involved in the way [Doctor's Data's] ***tests are reported***. How can you let them get away with ***using a false reference range to interpret their reports***? (Ex. 5 (Email 7/8/10), p.

DEF 02891 (emphasis added))

CLIA officials rejected the Barrett Defendants' claims against Doctor's Data, ***every time***. For instance, in July 2010, CLIA enforcement officials circulated an internal email, stating:

> ***I found no real problems with this lab. The urine metal reference ranges are reflective of the published CDC ranges***. Validation studies were performed on all of the analytes that I have reviewed. QC and PT are being performed with no real problems. ***I honestly do not see a problem with the testing***.

(Ex. 6 (Email 7/12/10), p. DEF 02896) (emphasis added); and, "I have inspected this lab at various times due to [the Barrett Defendants'] ***constant complaints***. ***We have only been able to cite standard level or no deficiencies at this lab with each onsite inspection***") (Ex. 7 (Email undated), p. DEF 02890) (emphasis added)).

CMS/CLIA's ongoing certification after "each onsite inspection" in the wake of Barrett Defendants' "constant complaints" is significant, if not dispositive, on the issue of the propriety of DDI's testing and its test results report format for provoked urine samples. As one of DDI's experts, Dr. Russell Jaffe, M.D./Ph.D., both a clinician and lab director, observes:

> The fact that at all times ... [DDI] has been and still is a fully accredited, inspected, and licensed clinical laboratory certified by CAP, CLIA, and the New York Department of Health, all three having standards which are rigorously enforced, affirms that Doctor's Data is a properly regulated and inspected clinical laboratory engaging in no wrongdoing, notwithstanding Defendants' specific accusations about fraudulent," "shady," or "misleading" practices. (Ex. 1 (Dr. J), p. 5).

Like CMS/CLIA, the one court that directly addressed the Barrett Defendants' claims that Doctor's Data's test report format for provoked urine specimens is misleading, fraudulent, and/or deceptive, rejected these claims outright. *Pfister v. Medical Wellness Institute, Doctor's Data, and Vinu Patel, M.D.*, No. 49D10-0802-CT-005046 (Marion County, Indiana). (Ex. 8 (SJ), p. 2). Indeed, in granting summary judgment in favor of DDI, the *Pfister* court stated: DDI provided "an explanation of the provided reference range . . . in bold lettering and in sufficiently clear terms for Pfister [the patient] himself to question the application of the reference range" to his provoked

urine specimen," in expressly rejecting the truth of the very same allegations made by the Barrett Defendants which DDI asserts are libelous here.

In addition to so holding, the *Pfister* court also emphasized that DDI was entitled to rely on the ordering physician to understand and explain the significance, if any, of DDI's findings identified in its test results report. Specifically, the *Pfister* court concluded:

> [DDI] did not owe Pfister [the patient] a duty of care to interpret the results of his [provoked] urine test. The level of interaction between Doctor's Data and Pfister is too minimal to impose such a duty. Doctor's Data did not order the urine test, determine how the urine should be collected, or determine whether Pfister should be injected with a provoking agent prior to the urine test. Further, Doctor's Data did not examine Pfister or have any information regarding the context in which the urine test was ordered…. Doctor's Data was not involved in making this diagnosis or in recommending any treatment. Instead, Doctor's Data provided the Report to Pfister's physicians who are qualified to interpret the results and offer a diagnosis…. [DDI] role was limited to testing Pfister's urine sample and reporting the results. [DDI] did not owe a duty of care to interpret those results. *Id.* at 2-3.

DDI's experts confirm the *Pfister* court's common sense conclusion. DDI's experts opine as a matter of clinical laboratory custom and practice, clinical laboratories, like DDI, are entitled to (and do) reasonably rely on an ordering physician to adequately understand and communicate the clinical meaning of the patient's test results to his patient to avoid any misunderstanding or confusion. (Ex. 1 (Dr. J), p. 9, 12; Ex. 2 (Dr. C), p. 11-12; Ex. 3 (Dr. B), p. 17) Indeed, per accepted industry custom and practice, DDI issues its test results report to the ordering physician, not directly to the physician's patient. (Ex. 2 (Dr. C), p.5)

C. Notwithstanding CLIA's On-Going Certification And The *Pfister* Court Ruling, The Barrett Defendants Continue Asserting That DDI's Test Results Format Is A "Fraud".

Notwithstanding the clear rejection by CMS/CLIA and the *Pfister* court of the truth of the libelous allegations about DDI which are at issue here, the Barrett Defendants continue their unabated assault on DDI's test results report for provoked urine specimens. Before the filing of this 2010 litigation *and continuing through this very day,* the Barrett Defendants still widely

disseminate their authored article, "*How the 'Urine Toxic Metals' Test Is Used to Defraud Patients*." (Ex. 9 (Cmplt Ex. A), p. 1) In this publication, the Defendants expressly reference "Doctor's Data" by name, calling it "a Chicago-based laboratory that caters to nonstandard practitioners," and reproduce a DDI's test results report for a provoked urine sample. *Id.* In so doing, the Barrett Defendants claim that the provoked "urine test is used to defraud patients" and is a "scam" because DDI's "report classifies the man's lead and mercury levels as 'elevated' because they are twice as high as the upper limit of their 'reference ranges'," which is "misleading" because the "reference range is based on non-provoked tests." *Id.*

Other examples of the Barrett Defendants' attack on DDI's test results report for provoked urine samples are legion. For instance, they have published on the Internet, "Doctor's Data's urine toxic metals test is a fraud." (Ex. 10 (Cmplt. Ex. C), p. 1) Moreover, they have publically proclaimed that DDI's "'Urine Toxic Metals' ***test is used to trick people*** into thinking that they have lead or mercury poisoning and need 'detoxification' with chelation therapy." (Ex. 11 (Cmplt. Ex. F), p. 1) (emphasis added) Defendants later affirmed these libelous claims in their depositions, testifying that DDI's urine test results report for provoked urine samples is "meaningless" and "not scientifically/medically interpretable." (Ex. 12 (Bt. Dep.), p. 187; Ex. 13 (Bz. Dep.), p. 196) In other publications, the Barrett Defendants characterize DDI as a "[s]hady clinic" to be avoided. (Ex. 14 (Cmplt. Ex. D), p. 1; Ex. 15 (Cmplt. Ex. G), p. 1)

D. The Barrett Defendants' Expert, Dr. Ruha, Has Proffered Opinions Relating To Doctor's Data's Test Results Report Format Without Any Experience, Knowledge, or Training In The Field Of Clinical Laboratory Science, Standards, Or Industry Custom And Practice.

To avoid the obvious implication of the CMS/CLIA findings, the *Pfister* court's holding and the unchallenged opinions of DDI's experts, the Barrett Defendants proffer Dr. Ruha as their "liability" expert to try to establish their aforementioned "truth" defense. Dr. Ruha memorialized her proffered opinions for this case in two documents. The first document is Dr. Ruha's article

entitled, "*Recommendations for Provoked Challenge Urine Testing*" ("*Recommendations* Article"). (Ex. 16 (Article), p.1) Dr. Ruha published this article before she ever knew about this case and without reviewing any case materials. (Ex. 17 (Dr. R Dep.), p. 18-27) Indeed, Dr. Ruha admits that (aside from reviewing a handful of DDI's test results report forms and associated DDI "commentaries") she reviewed no pleadings, no depositions, no expert disclosures, and no other discovery related to this case, prior to proffering any of her opinions in this case. *Id*. at 18-21. However, DDI is not seeking to bar Dr. Ruha's opinions in her *Recommendations* Article.

Rather, DDI's *Daubert* motion addresses Dr. Ruha's proffered opinions in her second provided document, a one page attachment ("Attachment Opinions"), to the extent that Dr. Ruha articulates therein opinions relating to DDI's test results report. In particular, Dr. Ruha opines, in pertinent part, as follows, which is the subject of this *Daubert* motion:

> In my personal experience as a treating or consulting physician, I have encountered dozens of individuals of varying age and sex who were concerned that they had metal toxicity or poisoning based on a provoked urine toxic metal test report from Doctor's Data. In these cases, the patient and/or medical healthcare provider indicated to me that they understood the graphic depiction of metal concentrations above the upper limit of normal to be diagnostic of toxicity. None of those patients or providers indicated that they understood anything on the report form to state that the reference ranges, graph, or other material on the report was to be ignored or was otherwise not applicable to their specific toxic metal level. * * * [I]t is my opinion that the report form used by Doctor's Data to report the results of provoked urine toxic metals tests can convince individuals that metal toxicity exists when appropriate tests to detect those metals demonstrate no elevation in the metal concentrations above a normal reference range;
>
> It is my opinion, based on my experience as a medical toxicologist receiving and reviewing Doctor's Data's provoked urine toxic metals test report that there is nothing within that report that effectively conveys that any portion of the report is to be ignored;
>
> My experience with patients and non-medical toxicology health providers who have been presented with a provoked urine metals test report form from Doctor's Data is that the result and graphical representation of the result create a diagnostic impression or inappropriately solidify a preexisting misconception that toxicity exists;
>
> My experience with patients and non-medical toxicology health providers who

> have been presented with a provoked urine metals test report form from Doctor's Data is that they appear to me to make their assessment of poisoning based partly on the result and graphical representation of the result. (Ex. 18 (Att. Ops.), p. 1)

The Court should bar Dr. Ruha's foregoing anecdotally limited opinions based on her own admissions. For instance, Dr. Ruha concedes she is ***not "an expert*** in the field of regulations that would be ***applicable to clinical laboratories***…. [she] is ***not an expert in clinical lab report forms… I have no expertise about labs***." (Ex. 17 (Dr. R Dep.), p. 64, 84, 91) (emphasis added). Indeed, Dr. Ruha possesses no general or specific knowledge, experience, or training in clinical laboratory regulations, standards, or custom and practice. *Id.* at 84. She is not aware that clinical laboratories are highly regulated by the federal government; she is not aware of any organization by name that regulates clinical laboratories, nor is she familiar with any published standard used by those regulating agencies. *Id*. at 64-65. Dr. Ruha does not know what the acronym "CLIA" stands for or what "CLIA" represents. *Id*. at 64. Dr. Ruha has never run, worked in, or been trained by a clinical laboratory; nor has she ever taught any classes on any subject matter that would address clinical laboratory sciences, standards, or practices. *Id.* at 63.

Moreover, Dr. Ruha did nothing to familiarize herself with the field of clinical laboratory science or practice prior to relaying her anecdotal experience with "dozens" of individuals. For instance, Dr. Ruha did nothing to familiarize herself with of any federal laws, regulations, standards, or practices that pertain to clinical laboratories. *Id.* at 65. Dr. Ruha did not review any metal toxicity report forms from any other laboratory besides Doctor's Data. In fact, Dr. Ruha has no recollection of ever seeing any other one. *Id.* at 53. Dr. Ruha did not review any documentation relating to national practices and procedures of other clinical laboratories.

Also, Dr. Ruha did not even review anything specific to this case prior to relaying her anecdotal experience involving dozens of individuals. For instance, she had no knowledge of CLIA's emails rejecting the Barrett Defendants' specific complaints relating to DDI's test report

form. *Id.* at 65-72. Similarly, she knew nothing of the *Pfister* court's summary judgment ruling in DDI's favor, concluding its Qualifying Statement on its test results report form was clear and not misleading, and further concluding—as a matter of law—that DDI is entitled to rely on an ordering physician to understand and adequately communicate the findings identified in DDI's test results report. *Id.* at 98. Likewise, Dr. Ruha did not review DDI's expert reports, those of Drs. Jaffe, Clark, and Bernhoft, which expressly explain why DDI's test results report form is not misleading and is consistent with clinical laboratory standards, regulations, and industry practice. *Id.* at 31, 37.

Instead, Dr. Ruha's aforementioned opinions are admittedly based solely on her anecdotal and limited interaction with a small group of individuals. *Id*. p. 132. In so opining, Dr. Ruha conceded that only some—***not all***—individuals would potentially misunderstand DDI's test results report. *Id.* at 84-85 (DDI's test result report for a provoked urine sample "[c]ould be misleading to some but not to others," is only "potentially misleading," and is ***not*** misleading to her because she understands its Qualifying Statement).

III. LEGAL ARGUMENT

This Court should bar Dr. Ruha's proffered opinions pursuant to *Daubert*, and Rule 702 of the Federal Rules of Evidence. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data, (c) the testimony is the product of reliable principles and methods, and (d) the expert has reliably applied the principles and methods to the facts of the case.

FRE 702; *accord, Daubert v. Merrell Dow*, 509 U.S. 579 (1993). Pursuant to Rule 702, a trial courts is a gatekeeper to prevent unreliable or unhelpful opinion testimony from being presented to the fact finder. *Chapman v. Maytag*, 297 F.3d 682, 686-87 (7th Cir. 2002). Rule 702 places three distinct substantive restrictions on the admission of an expert's opinion testimony: qualifications, reliability, and relevance. *Myers v. Ill. Central R.R. Co.*, 629 F.3d 639,644 (7th Cir. 2010); *Moore*

v. P & G- Clairol, Inc., 781 F. Supp. 2d 694 (N.D. Ill. 2011). The Barrett Defendants bear the burden of proving the admissibility of Dr. Ruha's opinion testimony by a preponderance of the evidence. *Jordan v. City of Chgo.*, 2012 WL 254243 *1 & 4 (N.D. Ill. 1/27/12).

As explained below, Defendants cannot, as a matter of law, meet their burden of proof. Specifically, Dr. Ruha's opinions should be stricken under Rule 702 and *Daubert* because the Barrett Defendants cannot prove: (1) that Dr. Ruha is ***qualified*** to opine about DDI's test results report; and (2) that Dr. Ruha's opinions are based upon ***reliable principles or methodology***.

A. Dr. Ruha Lacks Sufficient Qualifications To Opine On DDI's Test Results Report.

As an initial matter, Defendants cannot prove that Dr. Ruha is ***qualified to testify about DDI's test results report***. An expert may be deemed unqualified, despite having significant experience in an industry, where she lacks the knowledge and expertise "to offer the specific opinions [s]he proposes." *Driver v. Apple Il.*, 2011 WL 4007337 *5 (N.D. Ill. 9/9/11); *Myers*, 629 F.3d at 643-44. Indeed, as part of its gatekeeper function, the Court must ascertain not just whether "an expert witness is qualified in general, but whether his qualifications provide a foundation for [her] to answer a specific question." *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010).

Whether an expert is qualified to offer a proposed opinion is determined "by comparing the area in which [she] has superior knowledge, skill, experience, or education with the subject matter of her testimony." *Am. Honda v. Allen*, 600 F.3d 813, 816 (7th Cir. 2010). Thus, Dr. Ruha's opinion testimony relating to DDI's test results report is only admissible if she is qualified to so testify based on her knowledge, skill, training, education, or experience. *Erwin v. Johnson & Johnson*, 492 F.3d 901, 904 (7th Cir. 2007). Opinion testimony that goes beyond the expert's specialized knowledge is properly excluded. *Id.*; *Biondo v. City of Chi.*, 2002 WL 1160948 *3 (N.D. Ill. 5/31/02); *Daubert*, 509 U.S. at 597 (knowledge requirement governing admissibility guards against subjective or speculative opinions.).

Dr. Ruha admits she lacks the requisite qualifications – "knowledge, "training,"

"education," and "experience" – to opine on the propriety of DDI's test results report for provoked urine samples. Although an expert in toxicology (venom poisoning, (Ex. 17 (Dr. R. Dep.), p. 42), she is not an expert in clinical laboratory science, regulations, standards, or practice. Indeed, she frankly admitted in her deposition that she is "***not an expert in clinical lab report forms… I have no expertise about labs***." *Id.* at 64, 84, 91 (emphasis added). This testimony alone justifies barring her proffered opinions relating to DDI's test results report. 4 Weinstein's Fed. Evid. §702.06[1] at 702-52 (2000) (court should "exclude proffered expert testimony if the subject of the testimony lies outside the witness's area of expertise.").

Aside from her comprehensive admission of "not being an expert in clinical lab report forms [and] labs," Dr. Ruha's background confirms this fact. In particular, she lacks any specialized knowledge, experience, training, or experience, either: (1) generally, with respect to clinical laboratory regulations, standards, or custom and practice, or (2) specifically, with respect to clinical laboratory urine test result reports. For instance, she is unaware that clinical laboratories are highly regulated by the federal government; she is not aware of any organizations by name that regulate clinical laboratories; she is not familiar with any published standard used by any agency regulating clinical laboratories; she does not know what the acronym "CLIA" stands for or what "CLIA" represents; she has never run, worked in, or been trained by, a clinical laboratory; she has never taught any classes on any subject matter related to clinical laboratory sciences or industry custom and practice. (Ex. 17 (Dr. R. Dep.), p. 63-65, 84) She has not even reviewed another test result report for a provoked urine sample from any other clinical lab. *Id.* at 53. Based on these admissions, she is unqualified to opine on the propriety of DDI's test reports.

Indeed, Dr. Ruha's proffered core "expert opinion" regarding DDI's test results report reveals her lack of knowledge, education, training, and experience in clinical laboratory science and practice. The essence of her proffered opinions about DDI's test result report (like, the Barrett Defendants' libel) is based on a fundamental lack of knowledge about clinical laboratory test

reports. Specifically, she criticizes DDI's inclusion of reference ranges (applicable only to unprovoked urine samples) in its test results report for provoked urine samples. (Ex.18 (Att. Ops.) p.1) (individuals "appear to me to make their assessment of poisoning based partly on the result and graphical representation of the result" relative to reference ranges applicable to non-provoked urine and "nothing within that report . . . effectively conveys that any portion of the report [i.e., the reference range] is to be ignored"); (Ex. 17 (Dr. R. Dep.), p. 86-87, 90) (criticizing use of reference range applicable to unprovoked urine within results report for provoked urine sample because it can mislead patients and physicians into believing their heavy metal levels are above "normal," even though DDI expressly includes its Qualifying Statement).

Dr. Ruha's proffered opinion, however, is premised on a lack of basic knowledge. Federal law requires CLIA-certified clinical laboratories, like DDI, to include reference ranges on all test reports. (Ex. 2 (Dr. C), p. 7) But, there is no scientifically established or accepted reference range for provoked urine samples. So, DDI is compelled under federal law to include reference ranges applicable to unprovoked urine in its test results reports for provoked urine specimens with a corresponding "disclaimer" about the inapplicability of the reference ranges, if the specimen is a provoked urine sample. *Id*. Moreover, notwithstanding the Barrett Defendants' "constant complaints" about this practice, CLIA has found no impropriety after repeated inspections. (Ex. 7 (Email undated), p. DEF 02890) Similarly, DDI's clinical laboratory experts agree that DDI's practice and report is within industry standards and practice and is appropriate. (Ex. 2 (Dr. C), p. 7; Ex. 3 (Dr. B), p. 18-19)

Dr. Ruha conceded to knowing none of the foregoing. She is unaware that CLIA-certified laboratories, such as DDI, are required by federal law to include reference ranges in all test reports. (Ex. 17 (Dr. R), p. 82) ("I am not aware if they [reference ranges] are required"). Furthermore, the Barrett Defendants never disclosed to her their numerous e-mail exchanges with CLIA, or that CLIA found no deficiencies in DDI's reporting for provoked urine specimens, notwithstanding

Barrett' "constant complaints." *Id*. at 65-72. Similarly, she failed to review any report forms of provoked urine samples from any laboratory but DDI. In fact, she has no recollection of ever having seen any other test results report. *Id.* at 53. Moreover, she is unaware of the *Pfister* court's ruling relating to the non-misleading nature of DDI's Qualifying Statement. *Id.* at 98. She never reviewed any documents relating to accepted practices or procedures for any clinical laboratories.

Accordingly, the Barrett Defendants cannot prove that Dr. Ruha possesses the necessary knowledge, training, education, or experience to be a qualified expert relating to the propriety of DDI's test results report. To be sure, courts have not hesitated to bar comparable testimony. *Biondo,* 2002 WL 1160948 *3 (opinion barred because expert lacked an understanding of basic concepts employed by the City in making promotional decisions about which he was asked to opine); *Driver,* 2011 WL 4007337 *11 (restaurant consultant with 35 years in restaurant management barred from expressing opinions on restaurant industry practice, especially where his opinion was made without any consideration of the governing Department of Labor regulations, he did not conduct any industry wide search or consult with any publications to inform him on industry standards to which he was not knowledgeable). Thus, for these reasons as well, the Court should strike Dr. Ruha's opinions relating to DDI's test results report.

Any reliance by the Barrett Defendants on Dr. Ruha's "experience" (as opposed to her knowledge, training, and education) to prove her qualification to expertly opine should be rejected. When an expert's experience is the only qualifying factor, *Daubert* requires the court to determine whether the experience warrants placing that individual's views before the jury as an expert. *E.g. Jones v. Lincoln Elec.*, 188 F.3d 709, 723 (7th Cir. 1999) ("An expert's opinion based solely on experience...still must be an expert opinion - that is - an opinion informed by the witness' expertise rather than simply an opinion broached by a purported expert").

In the instant case, Dr. Ruha's "experience" falls far short of qualifying her as an "expert" in assessing the propriety of clinical laboratory reports. She admits her "experience" is extremely

narrow, being limited to a "treating or consulting physician" to "dozens" of individuals who received (from their primary physician, not DDI) a DDI test result report for a provoked urine specimen. (Ex. 18 (Att. Ops.), p.1; Ex. 17 (Dr. R. Dep.), p. 86) Moreover, she has never submitted a provoked urine sample to a laboratory (Ex. 17 (Dr. R. Dep.), p. 55-56), nor has she ever seen a test result report for a provoked urine sample from any other laboratory. *Id*. at 53.

Dr. Ruha concedes her experience represents a very small number of individuals who "did not understand" DDI's test results report, while many others, including other physicians, many patients, and her, do understand it and its Qualifying Statement. *Id*. at 84-85. Thus, based on her limited, anecdotal "experience" with clinical laboratory test reports for provoked urine samples, Dr. Ruha falls far short as a "qualified expert" to opine on the propriety of DDI's test results report.

Certainly, federal case law also supports denying the Defendant Barrett's reliance on Dr. Ruha's "experience" as a basis for finding her expertly qualified. For instance, the courts' decisions in *Rezulin* and *Moore* are illustrative. *See In Re Rezulin Products Liability Lit.*, 309 F.Supp.2d 531, 559 (S.D.N.Y 2004) (holding that "in light of expert's lack of formal training in diabetology or endocrinology, mere fact that some of his patients might have been exposed to drug [at issue in this product liability/negligence case] was insufficient to suggest that expert had specialized knowledge on risks and benefits of drug, which…he presumably had little occasion to prescribe"); *Moore*, 781 F. Supp. 2d at 700-704 (expert with several degrees in organic chemistry, extensive experience, Chairman of University Department's Committee on Lab Safety, and significant other experience dealing with chemical safety, barred under *Daubert* on issue of whether chemical product safety warning was adequate, where expert had no background experience or knowledge in any field related to the design of warning labels and had only minimal experience on what should appear on a warning label from his time working as a junior chemist).

Finally, Dr. Ruha also is not "qualified" as an expert because she has never provided trial testimony as an expert witness on any subject in any court, much less in the field of clinical

laboratory science, standards, or practice. (Ex. 17 (Dr. R Dep.), p. 7-14) For this reason too, in light of the foregoing analysis, Dr. Ruha's proffered testimony should be barred. *Biondo*, 2002 WL 1160948 *3 ("Although [the] court realizes there is a first time for every expert witness, the first time should occur when the proffered expert has the requisite 'knowledge, skill, experience, or education' as required by Federal Rule of Evidence 702.").

B. Dr. Ruha's Proffered Expert Testimony Regarding DDI's Report Also Lacks Reliability.

This Court also should bar Dr. Ruha's proffered opinions about DDI's test results report because they lack ***reliability***. A trial court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practices of an expert in the relevant field." *Kumho*, 526 U.S. at 152. As such, under FRE 702 and *Daubert*, an expert's reasoning or methodology underlying her testimony must be scientifically reliable. *Erwin*, 492 F.3d at 904.

Per these general principles, a district court should bar proffered opinion testimony as unreliable: (1) where the opinion is not based on sufficient facts and data (*Ortiz v. City of Chgo*., 656 F.3d 523, 526 (7th Cir. 2011)); (2) where the expert is relying upon her personal experience, but such personal experience does not reliably compel her conclusion (*Jordan*, 2012 WL 254243, *6; *Crawford Supply*, 2011 WL 4840965 *3); or (3) where such an opinion is based upon unreliable methods that are not reliably applied to the facts (*Chapman*, 297 F.3d at 687). *See generally Biondo*, 2002 WL 1160948 *4.

Here, Dr. Ruha's opinions regarding DDI's test results report trigger all of these concerns and thus should be excluded as unreliable for any number of reasons. Once again, as a general matter, Dr. Ruha's acknowledgment is dispositive: "***[I am] not an expert in clinical lab report forms… I have no expertise about labs***." (Ex. 17 (Dr. R. Dep.), p. 64, 84, 91) (emphasis added).

More specifically, Dr. Ruha also concedes her opinions regarding DDI's test results report are "not based on sufficient facts and data." Dr. Ruha's opinions are based solely on her limited,

anecdotal interaction with a very small group of patients, "dozens" ***over her career***, who previously received heavy metal provoked urine testing results from DDI. *Id*. at 68, 86. This compares to tens of thousands of provoked urine tests conducted by DDI ***each year***. As such, Dr. Ruha concedes her experience is a "small fraction of the population" who received provoked urine testing results from DDI. *Id.* at 68, 132-33. Indeed, Dr. Ruha's limited and anecdotal experience amounts to far less than .1% of those who supplied provoked urine samples to DDI for testing. *Id.* At the same time, Dr. Ruha admits that large numbers of patients and physicians ***do*** understand DDI's test results report and Qualifying Statement. *Id.* at 84-85.

Moreover, aside from her limited, anecdotal experience, Dr. Ruha ignored virtually every other conceivable source for relevant "facts or data." The universe of "facts" and "data" ignored by Dr. Ruha is vast, including: (1) no knowledge of clinical laboratory industry standards, regulations, and practices for test results reports (*Id.* p. 64-65, 84); (2) no knowledge of CLIA generally, or that CLIA specifically addressed the Barrett Defendants' complaints about DDI's test results report and found no problems (*Id.* at 65-72); (3) never working or training in any clinical laboratory (*Id.* at 63-65); and (4) never examining a test results report for a provoked urine sample from any other laboratory (*Id.* at 53). Based on the foregoing, Dr. Ruha's opinion testimony relating to DDI's test results report is not reliable, as it is not based on "sufficient facts and data," her personal experience "does not reliably compel her conclusion," and her opinions are "based upon unreliable methods that are not reliably applied to the facts."

Again, courts have barred substantively comparable opinion testimony. *E.g.*, *Driver,* 2011 WL 4007337 *6 (expert's opinion regarding certain tip practices in casual dining segments of the restaurant industry was limited to the specific types of restaurants he worked in. Because the expert made no "effort to make up for his gap in knowledge," the court determined one could not reliably conclude that his experience was representative of what is "customary" in the industry to which he was hired to opine and as such was unreliable); *Biondo,* 2002 WL 1160948 *5-6 (barring

as unreliable expert's use of an inappropriate comparison population that favored the party's position for which he was hired, which was an "inappropriate and flawed methodology"); *Chapman,* 297 F.3d at 688 ([p]ersonal observations are not a substitute for scientific methodology and are insufficient to satisfy *Daubert's* most significant guidepost."); *Superior Aluminum,* 2007 WL 4618463 *7 (citing *Kay v. First Continental Trading, Inc*., 976 F. Supp.2d 772, 773 (N.D. Ill 1997) (ruling that proposed expert would not be permitted "to report on random conversations that he had with colleagues."); *General Elec. v. Joiner*, 522 U.S. 136, 146 (1997) (district court may exclude expert testimony that is "connected to existing data only by the *ipse dixit* of the expert,"). Accordingly, because Dr. Ruha failed to "adhere to . . . standards of intellectual rigor" demanded to be an expert, her opinions regarding DDI's test results report also should be barred as unreliable.

IV. CONCLUSION

WHEREFORE, Plaintiff Doctor's Data requests that this Court bar testimony and opinions proffered by Defendants' expert, Dr. Ruha, relating to matters of clinical laboratory standards and practice, including her opinions relating to DDI's urine test results report and its allegedly misleading nature.

Respectfully submitted,

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